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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,465	04/13/2000	Robert F. Bencini	15916-261	7431

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EXAMINER

SCHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/548,465

Applicant(s)

BENCINI ET AL.

Examiner

Laura C. Schell

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,21,24,43-48,50-54,65,66 and 68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47,48,50-54 and 68 is/are allowed.
- 6) ☒ Claim(s) 20,21,24,43,44,65 and 66 is/are rejected.
- 7) ☒ Claim(s) 45 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Allowable Subject Matter

The indicated allowability of claims 20, 21, 24, 43, 44, 65 and 66 is withdrawn in view of the newly discovered reference(s) to Ebling et al. (US Patent No. 4,934,340) and Savage et al. (US Patent NO. 5,507,725). Rejections based on the newly cited reference(s) follow.

Drawings

New Formal drawings in compliance with 37 CFR 1.121(d) are required in this application because the reference numbers and lead lines appear to be hand-drawn. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24, 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Ebling et al. (US Patent No. 4,934,340). Ebling discloses an apparatus (Fig. 5),

Art Unit: 3767

comprising: an elongate body (Fig. 4, 10a) defining a proximal portion (near 14a) and a distal portion (12a) and including a wall (the wall is defined as the substance between the lumen of (18a) and the outer surface of 10a) defining an inner surface (inner surface of lumen (18a)), an outer surface (10a) and a lumen (18a) extending from the proximal portion to an aperture in the distal portion (col. 6, lines 6-9); a steering wire (20a) having a distal portion (near 12a); an anchoring member (24a) associated with the distal portion of the elongate body and secured to the steering wire (col. 1, line 66 through col. 2, line 3); a stiffening member (22a) associated with the distal portion of the elongate body and defining a distal end, the distal end of the stiffening member being directly secured to the anchoring member (col. 1, line 66 through col. 2, line 3); and an anti-tear device configured and positioned relative to the stiffening member so as to prevent the stiffening member from tearing through the elongate body when the stiffening member bends (col. 4, lines 1-5 discloses that multiple rings (24 and 24a) can be positioned throughout the catheter and be connected to the support member/stiffening member. Therefore, two of these rings, connected together by the support member constitutes the same device as the applicant's anti-tear device, and furthermore, provides the same function of the anti-tear device, to spread out the force and stress placed on the steering wire; see also col. 3, lines 41-45).

In reference to claims 43 and 44, Ebling discloses that the anti-tear device is secured to the stiffening member and is tubular (col. 4, lines 1-10).

Claims 65 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Ebling (US Patent No. 4,934,340). Ebling discloses an apparatus (Fig. 5), comprising:

an elongate body (Fig. 4, 10a) defining a proximal portion (near 14a) and a distal portion (12a) and including a wall (the wall is defined as the substance between the lumen of (18a) and the outer surface of 10a) defining an inner surface (inner surface of lumen (18a)), an outer surface (10a) and a lumen (18a) extending from the proximal portion to an aperture in the distal portion (col. 6, lines 6-9); a steering wire (20a) having a distal portion (near 12a) operably connected to the distal portion of the elongate body (Fig. 5); a stiffening member (22a) associated with the distal portion of the elongate body and defining a proximal end (col. 3, lines 40-45 disclose that the stiffening member (22a) runs parallel to the steering wire (20a) and therefore must have a proximal end like the steering wire); and an anti-tear device, defining a proximal end and a distal end, secured to the proximal end of the stiffening member such that the proximal end of the anti-tear device is located within the distal portion of the elongate body (col. 4, lines 1-5 discloses that multiple rings (24 and 24a) can be positioned throughout the catheter and be connected to the support member/stiffening member. Therefore, two of these rings, connected together by the support member constitutes the same device as the applicant's anti-tear device, and furthermore, provides the same function of the anti-tear device, to spread out the force and stress placed on the steering wire; therefore, one ring positioned proximal to the distal ring (24a) shown in Fig. 5 can be attached to the stiffening member (22a) at a more proximal location, as Ebling discloses that multiple rings can be used and attached; see also col. 3, lines 41-45); wherein the elongate body defines a distal end (12a) and at least a portion of the stiffening member is located proximal of the distal end of the elongate body (col. 3, lines 40-45 discloses that the

stiffening member (22a) runs parallel to the steering wire, and therefore would be located in the distal end as shown in Fig. 5, as well as proximal to the distal end).

In reference to claim 66, Ebling discloses that the elongate body defines a diameter (Fig. 5) and the stiffening member (22a) and the distal portion of the steering wire (20a) are substantially diametrically opposed from one another. (Fig. 5; also see col. 3, lines 40-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebling et al. (US Patent No. 4,934,340) in view of Savage et al. (US Patent No. 5,507,725). Ebling discloses the device substantially as claimed including an apparatus (Fig. 5), comprising: an elongate body (Fig. 4, 10a) defining a proximal portion (near 14a) and a distal portion (12a) and including a wall (the wall is defined as the substance

Art Unit: 3767

between the lumen of (18a) and the outer surface of 10a) defining an inner surface (inner surface of lumen (18a)), an outer surface (10a) and a lumen (18a) extending from the proximal portion to an aperture in the distal portion (col. 6, lines 6-9); a steering wire (20a) having a proximal portion (Fig. 4) that extends to the proximal portion of the elongate body (near 14a) and a distal portion (near 12a); and a stiffening member (22a) associated with the distal portion of the elongate body and defining a distal end; an anchoring member (24a) located within the wall of the distal portion (Fig. 5) of the elongate body between the inner surface and the outer surface, in contact with the wall and secured to the distal portion of the steering wire (20a) and the distal end of the stiffening member (22a); and a handle (Fig. 4, 40). Ebling also discloses that the bending assembly can be radiopaque to be used with radiographic monitoring of the position of the catheter tip (col. 5, lines 4-7). Ebling, however, does not disclose that the handle is adapted to pull the steering wire relative to the elongate body. Instead, Ebling discloses that the steering wire is a wire that contracts when a charge is applied, and the contraction pulls the distal end of the catheter in the direction of the contraction of the steering wire. Savage, however, discloses a catheter with a handle (Fig. 1, 16) that is adapted to pull the steering wire (24a and 24b) relative to the elongate body, and further discloses that the steering wires are attached to anchoring ring members (Fig. 5, 22), just as the steering wire in Ebling is attached to an anchoring ring member. Therefore it would have been obvious to one of ordinary skill in the art to have modified Ebling, by applying his bending assembly, comprised of the anchoring member, steering wire and the stiffening member, to other types of steerable catheters steered by a pull

Art Unit: 3767

wire, in order to provide the bending assembly and adapt it to other medical devices, as Ebling discloses that it can be applied to many other medical devices in which steering is needed (col. 7, lines 20-45).

Allowable Subject Matter

Claims 45 and 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 47-54 and 68 are allowed. Claims 47-54 and 68 do not distinguish themselves over the prior art as the prior art does not suggest an anti-tear device with a slot in it and which is not connected to the steering wire.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LCS

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Handwritten signature of Kevin C. Sirmons in cursive script.